

# TSCA Fluoride Litigation

OCSPP Briefing

March 31, 2021

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# Overview

- EPA is in litigation after OCSPP denied a petition submitted under TSCA section 21 requesting EPA to ban the purposeful addition of fluoridation chemicals in public drinking water systems.
  - Submitted by Food & Water Watch and the Fluoride Action Network
  - May be possibility of settlement now. Please keep that in mind during briefing.
- A two-week trial was held in June 2020.
- Plaintiffs' Burden of Proof: Must demonstrate by a preponderance of the evidence that the purposeful addition of fluoridation chemicals in public drinking water systems presents an unreasonable risk of injury to health or the environment. (TSCA Sec. 21(b)(4)(B)(ii))

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## TSCA Section 21

- Under TSCA section 21, any person may petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule, or order under authorities including TSCA section 6(a).
- Section 21 Petitions must:
  - Be filed in EPA's Office of the Administrator; and
  - Set forth the facts that are claimed to establish the necessity for the action requested.
- EPA must:
  - Grant or deny the petition within 90 days; and
  - If denied, publish rationale for denial in the Federal Register.

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The petition must be filed in EPA's Office of the Administrator, and set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days from the day the petition is filed with EPA. If EPA grants the petition, EPA must promptly commence an appropriate proceeding. If EPA denies the petition, the reasons for denial must be published in the Federal Register.

# TSCA Regulation of Fluoride

- There is presently no regulation of fluoridation chemicals under TSCA.
  - Community water systems in the U.S. use one of three additives for water fluoridation.
  - The three additives are:
    - Fluorosilicic acid; also referred to as hydrofluorosilicate
    - Sodium fluorosilicate
    - Sodium fluoride
  - All three fluoridation chemicals are on the TSCA Inventory (grandfathered on the original inventory).
  - None of the three were identified, using risk-based process, for inclusion on the 2012 or 2014 TSCA Work Plans.

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## SDWA Regulation of Fluoride

- Maximum Contaminant Level (MCL): 4 mg/L
  - Enforceable drinking water standard.
- Maximum Contaminant Level Goal (MCLG): 4 mg/L
  - This is a non-enforceable public health goal.
- Note that the U.S. Public Health Service (“PHS”) recommends an optimal fluoride concentration of 0.7 mg/L for the prevention of dental caries.
  - The decision to purposefully add fluoride to drinking water is made by municipal public ballot or State authorities.
  - Levels of fluoride in public drinking water that are over 4 mg/L would be due to naturally occurring fluoride or anthropogenic sources.

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The two fluoride levels are based on different health outcomes:

4 mg/L is Max Contaminant Level ... to prevent fluorosis, an adverse effect.

0.7 mg/L is to prevent dental caries...minimum needed to give health benefit.

## TSCA Section 21 Petition

- November 23, 2016

- The Fluoride Action Network, Food & Water Watch, and several other groups and individuals submitted a petition under TSCA section 21(a) to EPA.
- The petition asked the Agency to ban “the purposeful addition of fluoridation chemicals to U.S. water supplies” using a TSCA section 6(a) rule.

**Standard of Review:** Does the petitioner demonstrate that a specific use of fluoride presents an unreasonable risk of injury to health or the environment.

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In the petition, they argued that:

1. Fluoride poses a neurotoxicity risk at levels relevant to the U.S. population;
2. Recent epidemiological studies corroborate neurotoxic risk in Western populations;
3. These neurotoxic risks are supported by animal and cell studies;
4. Susceptible subpopulations are at heightened risk;
5. EPA policies require a reference dose/reference concentration (RfD/RfC) derivation and ten-fold uncertainty factor application when evaluating the risks;
6. Fluoride confers few benefits to public health;
7. The extent and magnitude of risk from fluoridation chemicals is large due to the loss of IQ points among the US population;
8. The consequences of eliminating use of fluoridation chemicals in public water systems are limited due to the prevalence of topical fluoride applications in toothpastes; and
9. There is a link between fluoride and elevated blood lead levels.

## Petition Response Pt. 1 - Legal

EPA denied the petition on February 17, 2017, based on legal and factual/scientific rationales:

- A petition for regulation of a chemical under amended TSCA
  - must address all conditions of use of the chemical, and petitioners only identified fluoridation chemicals' use in drinking water in their petition

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## Petition Response Pt. 2 - Factual/Scientific

- Petition did not demonstrate that added fluoride to drinking water presents unreasonable risk of injury to health or environment
  - Quality and Relevancy of Studies
    - many /most from non-U.S. populations (mostly China) where natural fluoride levels in water are much higher than in the U.S.
    - did not control for important confounding factors
  - No Neurotoxic Harm shown from fluoride exposure in US drinking water

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## Petition Response Pt. 3 – Factual/Scientific

- Claims Not Supported by Studies/Guidance presented or misrepresented EPA's *Guidelines on Neurotoxicity Risk Assessment*
  - Did not adhere to general risk evaluation principles, including systematic review
- Public Health Benefits: CDC named community *water fluoridation in the top ten greatest public health achievements of the 20<sup>th</sup> century*
  - Numerous federal studies show fluoride reduces dental caries

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## Lawsuit Filed

- On April 18, 2017, Food & Water Watch and the other petitioners filed suit under TSCA section 21 in the Northern District of California reiterating concerns about the risks of fluoride and arguing that EPA:
  - (1) Interpreted TSCA as placing onerous evidentiary burdens on citizen petitioners
  - (2) Dismissed studies on demonstrably false ground; and
  - (3) Failed to consider evidence presented through the framework of its *Guidelines on Neurotoxicity Risk Assessment*.

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Quote from Complaint: "(A) erroneously interpreted the Frank R. Lautenberg Chemical Safety for the 21st Century Act as placing onerous new evidentiary burdens on citizen petitioners, (B) dismissed studies relied upon by Plaintiffs on demonstrably false grounds, and (C) failed to consider the research on fluoride neurotoxicity through the framework of its Guidelines on Neurotoxicity Risk Assessment."

Judges denial of the motion to dismiss was based on a determination that a petitioner can request an unreasonable risk determination on any one single condition of use, or multiple conditions of use.

### Motion to Dismiss

In Fall 2017, EPA moved to dismiss the lawsuit based on the legal grounds identified in the response denying the petition. The court denied the motion.

### Motion to Limit Review

EPA then filed a motion to limit the scope of the court's review to the administrative record in the case, which was also denied.

## “De Novo Proceeding”

- Litigants here are granted what is called a “de novo proceeding.” The court held that this means:
  - (1) The court looks at everything with a fresh set of eyes; and
  - (2) New evidence may be collected and presented at trial.

## Discovery & EPA Fact Witnesses

- The parties conducted a subsequent period of fact discovery, including document exchanges, interrogatories, and depositions.
  - Plaintiffs Deposed:
    - Ed Ohanian (OW) on behalf of EPA (30(b)(6)); and two current EPA employees with experience/expertise in fluoride (Kris Thayer from ORD, Joyce Donohue from OW); and risk assessment under TSCA (Tala Henry from OPPT).
  - EPA Deposed: the Plaintiffs named in the complaint for standing purposes, amongst others.
- The parties also identified experts and conducted a period of expert discovery.

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This slide is limited to current & former EPA employees' participation in the trial. CDC employee, Casey Hannan was also deposed (30(b)(6)).

Plaintiffs also deposed current EPA employee who was the lead drafter for the 1985 Federal Register notice setting the fluoride MCL and is now in ORD.

Plaintiffs also deposed two former EPA employees/union officials (Dr. Bob Carton and Dr. Bill Hirzy) who were EPA union members in the 1980's who were vocal in opposition to the Fluoride MCL/MCLG of the time.

Dr. Bob Carton, former head of National Federation of Federal Employees (NFFE), Local 2050 here at EPA; Dr. Bill Hirzy, was a former EPA scientist in the chemicals office, and former organizer and charter of NFFE, Local 2050.

## Motions in Limine and Experts

- Motions in limine for the inclusion/exclusion of evidence, as well as pretrial briefs and other pretrial materials, were filed with the Court in December 2019.
- Both parties have expert witnesses in the following disciplines:
  - Epidemiology (for DOJ/EPA: Dr. Ellen Chang; Exponent)
  - Toxicology (for DOJ/EPA: Dr. Joyce Tsuji; Exponent)
  - Risk Assessment (for DOJ/EPA: Dr. Tala Henry)
  - Benefits of Fluoride (for DOJ/EPA: Dr. Gary Slade) – Eliminated after Court granted plaintiffs motion in limine.

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Motions in limine: asking the court for an order or ruling limiting or preventing certain evidence from being presented by the other side at the trial of the case.

## Trial Schedule

- Pretrial conference was held in May of 2020.
- A virtual trial (due to COVID-19) was scheduled for two weeks, held June 2020. It was open to the public via Zoom webinar.
  - To best of my knowledge it was the 1<sup>st</sup> full trial held via video conference.

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## Trial

- Trial commenced with both sides calling experts to testify on the science behind fluoride's neurodevelopmental effects.
- At the close of the two-week trial, the Court made a few observations:
  - (1) it remained highly doubtful that petitioners have standing;
  - (2) the administrative record (i.e., the petition) was outdated, did not represent the evidence heard in this case, and none of the key studies discussed in this case were cited in the Plaintiffs 2016 petition; and
  - (3) the Court, albeit mistakenly, believed EPA was trying to hold petitioners to a higher standard of risk than it does for its own risk determinations
- The Court asked the parties to confer on a possible remedy/settlement.

## Takeaways/Implications if Court Issues Decision

- (1) If Judge rules in favor of Plaintiffs, will be overturning longstanding position of the federal government bolstered by science, that there is a health benefit to community water fluoridation.
- (2) Court will be standing in EPA's shoes in making risk determination.
  - Bypassing (I) TSCA section 6(b) risk evaluation requirements; (II) extensive public comment and peer review requirements; and (III) possibly science requirements under TSCA section 26.
- (3) Court held that when there is a trial, pursuant to TSCA Section 21, for initiation of a new rulemaking proceeding, the statute requires a "de novo proceeding," which permits the addition of facts not previously included in the initial petition submission.

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(1) The health benefit is caries prevention.

(2) While EPA has to follow particular statutory requirements, including best available science, weight of scientific evidence (including systematic review), the judge could potentially rule in favor of plaintiffs even though they did not meet these requirements.

(3) This is not the case for a petition to amend a rule.



## Settlement Options

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## Post-Trial

- The court issued an order on August 10, 2020 placing the case in abeyance.
  - The order: (1) acknowledges “that there are serious questions regarding whether the named Plaintiffs in this case have standing”;
  - (2) explains that the evidence presented at trial is very different than that underlying the 2016 petition;
  - (3) cites to the upcoming NTP systematic review of the epidemiological literature related to fluoride and neurotoxicity, which will help answer the questions before the court; and
  - (4) puts the case in abeyance, while urging Plaintiffs to submit an updated petition that fixes their standing issues and includes newly updated data and research for EPA to consider.
    - Later amend this part, at EPAs request, to require plaintiffs to seek leave of the court to amend the complaint.

## November 2020 Supplemental Petition

- Plaintiffs submitted a supplement to the original 2016 petition, asking EPA to reconsider its 2017 denial.
- The supplement included: (1) the trial record; (2) the National Toxicology Program's (NTP) draft Monograph entitled: *Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects*; (3) an unpublished pooled benchmark dose analysis; and (4) an op-ed authored by Drs. Bruce Lanphear, Christine Till, and Linda Birnbaum.

## EPA's Response

- On January 19, 2021, EPA declined to exercise its discretion to reconsider the 2017 petition denial. Below are the reasons for denial.

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## Motion for Leave to Amend Complaint

- Plaintiffs have since filed a motion seeking to amend their complaint to add a new standing witness, along with new information that has come out during trial.
- EPA's reply to the motion was filed on March 26<sup>th</sup> and the hearing is April 22<sup>nd</sup>.

Possibility of Settlement

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